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14. ABSTRACT Prostate cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death. However, screening asymptomatic men remains controversial, as early diagnosis and treatment of PCa has not yet demonstrated reduced disease-related mortality in a randomized trial. The goal of the current study is to develop and assess widely accessible, easily disseminable methods to assist men in making informed decisions about PCa screening. We will compare the efficacy of a new web-based, interactive decision support approach to our existing print-based PCa screening decision tool, among a diverse sample of male primary care patients. Abundant evidence documents the expanding role of the Internet in increasing access to and understanding of health information and the need for systematic evaluations of Internet-based interventions. To date, an Internet usage feasibility study was conducted; the print-based booklet has been significantly revised and updated; the research team has met with our team of web developers to formulate development of the Internet-based website; a list of free Internet access points has been compiled; and focus group participants have been accrued.					
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INTRODUCTION

Prostate cancer (PCa) screening is controversial, as early diagnosis and treatment of PCa has not yet demonstrated reduced disease-related mortality in a randomized trial.^{1,2} The primary question is whether PCa screening results in overdiagnosis, the detection and treatment of disease that would not otherwise result in increased morbidity or mortality. The Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial³ is designed to address this question, but results will not be available for at least 10 years. At present, the lack of evidence for effectiveness and the resulting controversy have not deterred PCa screening, as the practice of screening asymptomatic men is increasing in the U.S.⁴⁻⁶ Most men who undergo PCa screening are not making fully-informed decisions, as they are unaware of the controversy and believe that the medical community unequivocally accepts the benefits of screening.⁷⁻⁹ This issue is not unique to PCa as the difficulty of making medical decisions prior to the availability of definitive outcome data has been a long-standing issue in cancer screening.^{10,11} Importantly, this issue is likely to become increasingly significant as screening technology advances more rapidly than our ability to validate it.¹¹⁻¹⁵ Thus, widely applicable approaches to health education are needed in order to facilitate informed decision making about the growing number of unproven treatment and screening technologies.¹⁶⁻¹⁷ The goal of the current study is to develop and assess a widely accessible and disseminable method to assist men in making informed decisions about PCa screening.

Specific Aims: 1) Evaluate the impact of the delivery method (Web vs. Print vs. Usual Care) on the key patient outcome variables of knowledge, decisional satisfaction, health-related quality of life (HRQL), and the screening decision. 2) Assess factors that moderate the interventions' impact on the primary outcomes, including commitment to screening (defined by screening history and decisional balance), computer literacy, and age. In exploratory analyses, we will evaluate baseline factors that are related to use of the website by tracking the topics accessed and the amount of information reviewed. Study Design: In Phase I (months 1-6), we will develop an interactive, Internet-based, patient information and decision aid. In Phase II (months 7-36), we will evaluate the impact of this decision aid in a randomized controlled trial with male primary care patients aged 45-70 (N = 600). Trial arms include: 1) print-based information and decision aid (Print), 2) web-based information plus interactive decision aid (Web), and 3) usual care (UC). Subjects will complete outcome assessments at baseline, 1- and 12-months post-baseline. Relevance: This research has the potential to make several significant and innovative contributions: 1) the development and evaluation of a widely-disseminable method of educating a heterogeneous group of patients about a controversial topic, which can be adapted for other similarly contentious issues, 2) a determination of whether Web based materials are a feasible method of patient education for this age cohort, compared to print materials, 3) a determination of who among the target population benefits the most from a web-based intervention, and 4) the information required to streamline and target future web-based educational interventions.

BODY

Although we have completed a number of tasks, we have not completed everything that we had planned at this point. This is due in part to the confusion on our part regarding the start date of the grant. As you know, we have also received funding from the NCI to conduct this study, which allows us to add an accrual site, significantly enlarge the sample size, and add a specific aim over the course of a five year study. However, the NCI funding did not begin until March 1, 2006. I had thought that a formal request had been made by Georgetown to the DoD to have the same start date. However, I recently learned that it had not been changed, and thus we are 4 months behind, according to the original start date of December 1, 2005. However, we still expect that the project will be completed on time.

A second cause of our slower than anticipated progress is that our consultants, experts in prostate cancer screening (Steven Woolf, M.D., and Alex Krist, M.D.) and health communication (Janet Ohene-Frempong, M.S.), all suggested significant modifications to our existing print booklet. This is the booklet that we have tested in our study on prostate screening that began in 2004. We were not planning on needing to change it

significantly and therefore had not allotted the time on the grant to do it. However, their suggestions were very good and we felt it would be a mistake to ignore them. As a result we spent three months holding meetings, rewriting the booklet, sending it to our consultants and research team members for edits, all in an iterative process. Although we had an excellent booklet to start with, it is now much improved (see Word version attached). The overall changes that have been made include: 1) removing the focus of the booklet from a debate between doctors to a focus on the difficult decision that men must make; 2) a reduction in the reading level; 3) increasing the use of bulleted text in place of text in paragraph form; 4) moving the more technical graphs and figures toward the end of the booklet, so that those men who want to focus on these details can do so, without possibly putting off those men who don't want to read more complicated information; and 5) the screening procedures are now listed in a step by step fashion, clearly demonstrating what will happen if a man chooses to be screened. The development of the website could not occur simultaneously with the rewriting of the booklet, as the content of the print and website must be consistent. Thus, it did not pay to begin the website development if it was going to need to be significantly changed once we had finalized the booklet. We have given the website developers the revised booklet on which they are basing the website. We expect to have a final version of the website by the end of February. Once we have the final version of the website (or are very close to the final version) we will send the booklet to our graphic designer for it to be put in its final version before printing.

Summary of progress on the website development

As of December 21, 2006, Triad Interactive has reached the following milestones in development of the interactive Web site for this project:

- Completed analysis of revised booklet content
- Completed initial interface design
- Completed initial navigation scheme
- Completed database design

During November and December 2006, we have been concentrating on review of the revised booklet content and how the revised content can be best translated to an engaging, interactive Web-based experience. We have focused our efforts on designing the overall user experience including graphic user interface design and navigation scheme.

For the back-end database, we have a firm commitment to use Microsoft's free SQL Server Express 2005. The initial database schema is complete, tracking all user activities and responses throughout the program. (Users are identified only by a participant ID. No personal information is stored on the server at Triad.) Final reporting formats will be determined during Q1 2007.

Milestones we anticipate reaching during January, 2007:

- Audio script draft and review
- Client review and approval of interface design
- At least 50% of the content in place and available for review

A third reason for our slower than expected progress is that we needed to conduct another feasibility study regarding the internet capabilities of our target sample, men in the primary care clinics at Georgetown University and at the Washington Hospital Center. We realized that it had been 18 months since the feasibility study that was included with the grant application had been conducted and given the rapidity with which computer and internet capabilities change, we needed to get an understanding of where our sample was on these variables (see Table in Appendices). Thus, although this was not anticipated in the grant application, we needed this information in order to effectively plan our website. For example, we have been debating whether the website should be designed for a dial-up internet connection or for a broadband connection. There are pros and cons to either decision: if we choose broadband, some dial-up users will experience the website as much slower than is ideal, possibly causing them to give up on viewing the website. Alternatively, designing it for

dial-up users will mean that when the study is completed, the website would be out of date, as the technology and people's access to it will have been progressing the entire length of the study. Ultimately, we and the web developers have decided that we will design a website that is primarily designed for broadband users, but that we will conservatively include items that are known to slow the viewing experience (e.g., extensive video and audio). We have developed a list of locations for free internet access in the Washington DC metropolitan area that men can access if they do not have access to other convenient ways to use the website.

Below are our findings from the feasibility study, conducted in May-June 2006. See Results table in Appendix.

Internet Feasibility Study: We sought to determine the extent to which the target sample for the proposed study (male primary care patients aged 45-70), 1) used a computer at work or home, and 2) had personal access to the Internet, and 3) would be willing to access health-related information on the Internet. We accrued men in the waiting rooms of the primary care clinics at Georgetown University Medical Center (GUMC; N = 50) and at the Washington Hospital Center (WHC; N = 49). After signing the consent form, men completed a brief, written questionnaire. We approached 130 eligible men, of whom 99 agreed and provided usable data. The participation rate was 76%. At GUMC, the mean age was 54 years (SD = 7.5), 78% were married, 86% had completed some college or more, 28% were African American and 52% were white. At WHC, participants were an average of 55 years old (SD = 7.3), 30% were married, 51% had completed some college or more, 76% were African American and 20% were white. Regarding computer use and Internet access, 92% of GUMC and 43% of WHC men used a computer at home. Of those who did not have a computer at home, 25% (GUMC) and 14% (WHC) used a computer at work. The majority of those with Internet access at work could also go on-line for personal use, 100% (GUMC) and 92% (WHC). The majority of men connect to the Internet via high-speed connection, 85% (GUMC) and 57% (WHC). Regarding frequency of use, 66% of men reported using the Internet a few times a month or more at home and 41% use the Internet several times per week or more at work. Of those without a high-speed Internet connection at home or work, 33% (GUMC) and 45% (WHC) indicated a willingness to go to another location to obtain access. For those not comfortable accessing the Internet on their own, 58% (GUMC) and 72% (WHC) said they would ask a friend or family member for help using our PCa website. A majority of GUMC men prefer to receive health-related information from the Internet (72%) compared to a booklet (28%), while WHC men prefer a booklet (69%) over the Internet (31%).

We worked with the DoD Human Subjects officer from February through October to obtain approval of our procedures and documents. We received final approval on October 26, 2006. We also obtained Georgetown University IRB approval during this time.

Below we have inserted Task 1 from the Statement of Work and indicated progress made on each item.

Task 1. Develop the educational website

- a. Meet with entire team and Triad Interactive to begin process of web development. *We have met with Triad several times to discuss our ideas for the website and our goals for what the website will accomplish.*
- b. Hold 2 focus groups to assess men's preferences for web-based learning. *We are awaiting an initial draft of the website so that we can show both the revised booklet and the website to men in the focus groups. We expect to hold the groups in late January/early February. We have begun to accrue the names of men who are interested in participating in the focus groups. We are particularly interested in including men with limited literacy and have accrued 7 interested men from adult education centers.*
- c. Continue to work with Triad, providing feedback to them regarding the developing website and decision aid. *We expect that the final version of the website will be available in late February/early March.*
- d. Meet with our Department of Medicine collaborator (Dr. Fishman) to confirm the procedures for patient accrual. *We have met with Dr. Fishman regarding the accrual of subjects for the recent*

feasibility study, and will meet with her again in February to finalize the plans for the randomized trial.

- e. *Finalize the questionnaires to be included at each of the three assessments. The questionnaires to be included are largely the same as proposed in the grant. We have not learned of any newly developed measures that would be useful to include. We have attached the baseline interview which includes the measures.*
- f. *Develop subject tracking system using an Access database. We have a draft of the tracking system, which is based on our existing longitudinal study of prostate cancer screening participants. The assessment points are the same in both studies (baseline, one month post intervention and 12 months post intervention) and therefore will be basically identical to our existing tracking system.*
- g. *Develop database for data entry of the interviews. Similarly, the measures that we plan to use overlap almost entirely with our ongoing study of prostate cancer screening participants. Therefore, this is essentially completed as well.*

Key Research Accomplishments

- 1) A feasibility study on Internet usage was conducted at both Georgetown University (N = 50) and the Washington Hospital Center (N = 49). See description above and table in the Appendix.
- 2) The educational booklet, *Making an Informed Decision*, has been significantly revised and updated with the input of study consultants. See description above and attached booklet.
- 3) The research team has met several times with our team of web developers, Triad Interactive, to formulate the development of the interactive Internet-based website.
- 4) A list of free Internet access points in DC, MD, and VA has been created for men who do not have Internet access at home.
- 5) We have contacted area adult education centers to recruit men into low-literacy focus groups for the review of print and web-based educational tools. Seven eligible men have expressed an interest in participating.
- 6. IRB approval from the Department of Defense and Georgetown University IRB.

Reportable Outcomes – (see Appendices)

- 1) Revised Print Booklet
- 2) Results table from the Internet Feasibility study
- 3) Telephone interview

Conclusions –

The revised print booklet has many strengths that the previous version did not have, while maintaining its original strong points. It is better organized and easier to read, while maintaining a level of detail for those men who wish to delve deeper into the topic.

The feasibility study demonstrates men's computer/Internet access, their willingness to participate in an Internet-based study, and our access to the primary care clinics where we propose to accrue participants. It has also increased our awareness of the potential for difficulties that some men face when attempting to gain up to date health-related information from the Internet. This information has been extremely important in helping to guide the development of the website.

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Appendices

- 1) Revised Print Booklet
- 2) Results table from the Internet Feasibility study
- 3) Telephone interview

11/9/06

front cover*****

Prostate Cancer Screening: Making the Best Choice

Lombardi Comprehensive Cancer Center

Georgetown University Medical Center

Washington Hospital Center

page one*****

Prostate Cancer Screening: Making the Best Choice

Getting tested for prostate cancer is something that many men do faithfully each year. On the other hand, there are some men who have decided not to get screened, and others who have not yet made a decision either way. Regardless of which group you are in, you may be wondering why you should spend time reading a booklet about making a choice about prostate cancer screening.

Don't doctors already know that prostate cancer screening saves lives and that men should get screened every year?

The answer may surprise you. Based on current medical knowledge, *we don't know* whether prostate cancer screening saves lives. We do know that screening can *find* prostate cancer in its early stages. But, we don't yet know whether finding prostate cancer early will *reduce deaths* from prostate cancer. The research needed to fully answer this question will not be completed for several years.

What we do know is that all men should understand the pros and cons of prostate cancer screening to make an informed decision for themselves. Whether to be screened for prostate cancer is an individual choice. Your decision should be based on the facts that you learn, discussions with your doctor, and your own feelings and beliefs. After going through this process, some men prefer to be screened, some men prefer to not be screened, and some men want their doctor to decide.

This booklet will help you to understand what is known and what is not known about prostate cancer screening. In addition, we provide a worksheet (on p. XX) to help you consider your own preferences about prostate cancer screening.

Reading this booklet will help you to do many things:

Know the basics about the prostate

- ❖ Facts About the Prostate Gland and Prostate Cancer XX

Understand why there is no right or wrong choice about prostate cancer screening

- ❖ What is Screening and Is it Right for You? XX-XX

Learn the facts about prostate cancer screening:

- ❖ Getting Screened for Prostate Cancer: What Will Happen If You Decide to Get Screened XX-XX

Find out about the different treatments for prostate cancer

- ❖ Treatment Issues: Facts You Should Know If Prostate Cancer is Found XX-XX

Steps you can take:

- ❖ **Know** the Risk Factors for Prostate Cancer XX
- ❖ **Learn** the Symptoms of Prostate Cancer XX
- ❖ **Talk** with Your Doctor About Screening: Ask Questions XX

Decide How You Feel and What's Important to You

- ❖ Worksheet for Making Your Screening Decision XX

Learn more about the research and statistics of prostate cancer

- ❖ Beyond the Basics: Statistics and Research Issues XX-XX

Additional sources for information about screening

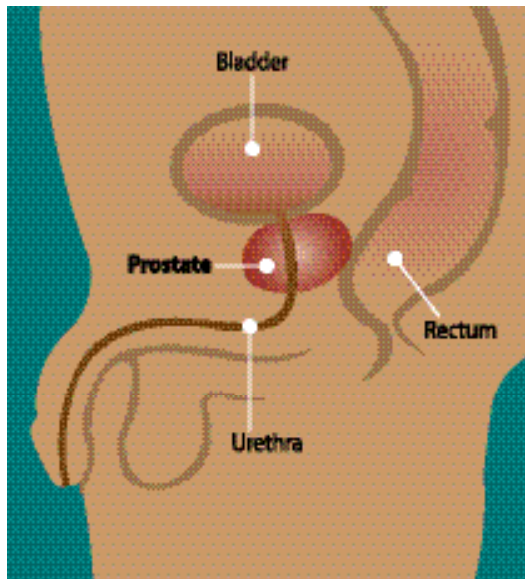
❖ **Find out more:**

1. National Organizations XX
2. Glossary for definitions of **boldface** words XX-XX
3. Selected References for related articles XX

Facts About the Prostate Gland and Prostate Cancer

What is the prostate?

The prostate is a gland in men that makes the fluid that carries sperm. It is located in front of the rectum and just below the bladder. It's about the size of a walnut.



What kind of prostate problems can a man have?

Benign Prostatic Hyperplasia (BPH)

BPH is enlargement of the prostate. BPH is not cancer. As men age, the prostate tends to increase in size. This can cause the urethra to narrow and decrease urine flow.

Prostatitis is an inflamed prostate, usually due to an infection. Prostatitis is not cancer.

Prostate Cancer

Prostate cancer occurs when prostate cells do not grow normally. The cells divide and create new cells that the body does not need. These cells form a mass of tissue called a tumor and can spread elsewhere in the body.

What is Prostate Cancer “Screening?”

Before going into the details of prostate cancer screening (p. xx), we want to give you some basic information to get started. Screening means looking for signs of disease in people who have no symptoms, when the disease is in its earliest stage. The main screening tests for prostate cancer are the:

- Digital rectal examination (DRE)
- Prostate specific antigen (PSA) test

The DRE and PSA tests cannot tell if you have cancer; they can only let you know if you need to have further tests.

Screening Recommendations

The American Cancer Society recommends that screening should be offered every year:

- to men who are likely to live at least 10 years
- beginning at age 50 for the general population
- beginning at age 45 for African-American men, and men who have a father or brother with prostate cancer

Not all organizations agree with these recommendations. For example,

- The United States Preventive Services Task Force states that there is *not enough evidence* to make a recommendation. The USPSTF concludes that evidence is insufficient to determine whether the benefits of prostate cancer screening outweigh the harms of screening.
- The American Urological Association states that decisions regarding screening for prostate cancer should be individualized. Benefits and consequences should be discussed with the patient before PSA testing occurs. Not all men over age 50 years are appropriate candidates for screening. Physicians should consider the patient’s age and other illnesses, as well as men’s preferences for the relevant potential outcomes.

The fact that major organizations differ is just one sign that we don’t yet have all of the answers about prostate cancer screening. Unfortunately, the differing opinions of these organizations can make it hard for men who are trying to make a decision. Since there is no right or wrong answer, this booklet is meant to help you make the best decision for yourself.

Will getting screened for prostate cancer help you?

Based upon current medical knowledge, there is no way to be certain how screening will affect your life. This can be confusing or unsettling information, because **we have been taught to find problems early and then to treat them.** Most people believe that *all* cancers will lead to pain and death, unless they are found early and are treated right away. Indeed, this is true in some, but not all, cases of cancer.

What is surprising to many people is that **not all prostate cancers cause health problems and death.** This may be hard to believe or accept. But, here are some facts you should be aware of:

Some prostate tumors become a very serious health problem.

- These tumors grow quickly.
- They spread beyond the prostate.
- They *can* cause illness and death.
- *Almost 30,000 men die each year from prostate cancer in the U.S. Prostate cancer is the third leading cause of cancer-related deaths among men. Prostate cancer can be a very serious and fatal disease.*

Most prostate tumors never cause big problems.

- These tumors grow slowly.
- They never become a serious health problem.
- They usually don't cause any symptoms during the man's life and the man dies of something else.
- *Autopsies on men who have died from causes other than prostate cancer have shown that up to 60% of men over the age of 60 had prostate cancer and did not know it. For these men, prostate cancer had never become bothersome enough to be diagnosed.*

Unfortunately doctors do not yet know how to figure out which prostate cancers will spread and which will not. If we could accurately predict which cancers will grow, then we could treat only these patients. *This issue is at the heart of understanding how prostate cancer screening can help and how it can cause problems.* Men need to understand both the advantages and disadvantages of prostate cancer screening to make an informed decision.

Is screening right for you?

The choice is yours.

Below are two examples of what men have said about prostate cancer screening. It is important to know that although they made different decisions, neither man has made a wrong decision. That is because their decisions are based on their personal beliefs.

Some men who decide to be screened have said the following:

“I will take the screening tests because they will give me peace of mind. It could mean finding a problem, taking further tests, and treating a potentially serious prostate cancer. And because there’s no way to tell if the prostate cancer will cause problems in the future, I want it found early when treatments might be more effective. I think that the possible benefits of screening outweigh the possible harms of screening.”

Some men who decide not to be screened have said the following:

“I will not take the screening tests until medical experts agree that finding and treating prostate cancer in its early stages will reduce my chances of dying from prostate cancer. Screening tests could lead to unnecessary tests and treatment of a prostate cancer that may never cause me problems. And treatment can have serious side effects. I think that the possible harms of screening outweigh the possible benefits of screening.”

This booklet is meant to help you make the best decision for yourself. To help you decide, let’s begin with the basics about screening.

**Getting Screened for Prostate Cancer:
What Will Happen
If You Decide to Get Screened**

Prostate Cancer Screening: The Basics

Steps involved in screening

Screening for prostate cancer can involve a number of steps. What happens in the first step affects what happens in the next step.

First Step: What to expect if you get screened

1. The DRE: A Doctor's Exam

- **DRE** stands for **D**igital (finger) **R**ectal **E**xamination.
- It is a quick exam for checking the health of the prostate.
- For this test, a doctor inserts a gloved and lubricated finger into the rectum.
 - This allows the doctor to feel the back portion of the prostate.
 - Your doctor will feel its size and any irregular or abnormally firm areas.
- The DRE is a brief procedure which can cause some discomfort.

2. The PSA: A Blood Test

- **PSA** stands for **P**rostate **S**pecific **A**ntigen.
- PSA is a substance produced by cells from the prostate gland. The prostate gland releases it into the blood.
- The PSA test measures the level of PSA in the blood.
- As a rule, the higher the PSA level in the blood, the more likely it is that a prostate problem is present.
- However, many factors, such as older age, BPH, and African American race, can increase PSA levels even when prostate cancer is not present. Further, some prostate glands produce more PSA than others, meaning that some men will have elevated PSA levels but will not have prostate cancer.

Next Step: Discussing the Results with Your Doctor

Because many factors can affect PSA levels, your doctor is the best person to interpret your PSA test results. Here are some commonly asked questions:

1. What is the normal range for a PSA test?

Most men have PSA levels under 4. A PSA level under 4 is considered a normal PSA level by most doctors. However, some research has suggested that what is considered normal should be lower than 4. Some doctors use different PSA ranges, depending on a man's age and race (see p. 24 for more information).

2. How accurate are screening tests?

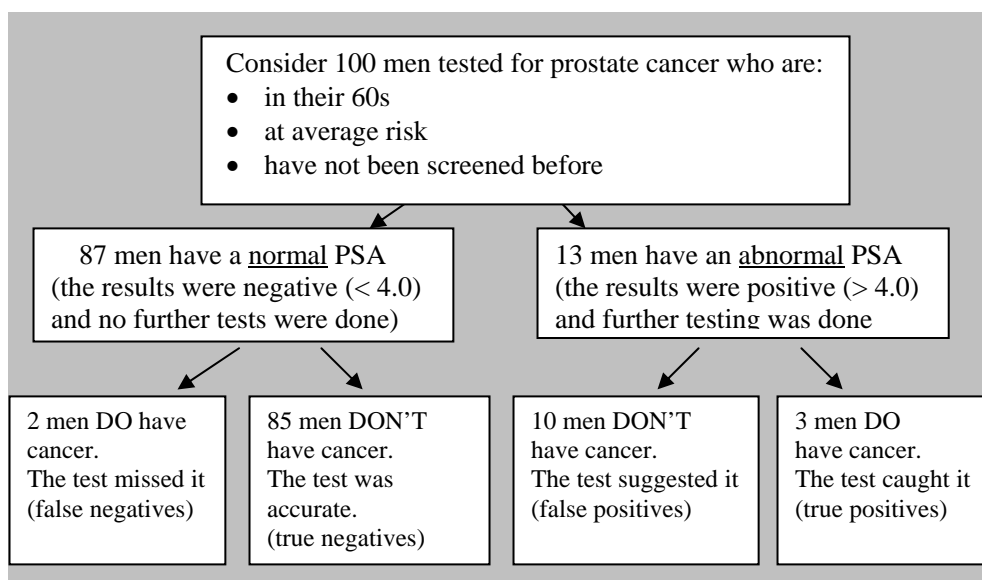
No test is right all the time. The same is true of the PSA test and DRE. The PSA test is better at finding small cancers, or cancers that cannot be felt by the DRE. The DRE can sometimes help find cancers in men with normal PSA levels. Both tests are often performed, although some men and clinicians choose to use only the PSA test.

- **False Positive Results**

- This happens when your results are abnormal, but you really DO NOT have cancer.
- So, the screening results can suggest that you have a cancer that is *not* really there.
- This can cause you to worry and have further tests that you may not need.

- **False Negative Results**

- This happens when your results are normal, but you really DO have cancer.
- So, the screening tests can also miss finding a cancer that *is* really there.
- This can cause you to relax and fail to have further tests that you may need.



3. What if the *first* set of screening results is *abnormal*?

This could mean one of many things:

- The results may be wrong and further testing will show this.
- The abnormal PSA results may be due to a non-cancerous condition, including benign prostatic hyperplasia (BPH), prostatitis, or recent medical procedures you may have had (such as cystoscopy or catheterization).
- You may have prostate cancer. *However, remember that most men (approximately 75%) who have an abnormal screening result DO NOT have cancer.*

Final Step: If the Test Results Are Abnormal

This next section describes what will happen if you have an abnormal prostate cancer screening result. This will help you know a little more about follow-up testing before you make a screening decision.

1. A Repeat PSA Blood Test

- If your PSA test or DRE was abnormal, your doctor may suggest a repeat PSA test. He or she may also test for the level of 'free' PSA (see p. 23).
- This will help to see if the earlier test was accurate. In addition, a repeat PSA test can determine whether the PSA level changes over time. Doctors refer to this as the PSA velocity (see p. 23 for more details).
- If it is still high, your doctor may refer you to a urologist. This is a doctor who has special training in problems related to the prostate.


2. An Ultrasound Test:

- The urologist may perform a TRUS. This stands for **TransRectal UltraSound**.
- A small lubricated probe is inserted into the rectum.
- The probe has sound waves that bounce off the prostate. This produces an image that the doctor can see on a video screen.

3. A Biopsy During the Ultrasound

- If the urologist suspects cancer, tiny samples of the prostate may be removed with a needle during the TRUS procedure. This is called a biopsy.
- The biopsy is usually performed in the urologist's office.
- The samples are examined under a microscope to determine if cancer cells are present.

4. A Discussion with Your Doctor

- If the biopsy results are normal: You probably do not have cancer. (Just like the PSA and DRE, biopsies are not 100% accurate, but they are the best method we have for determining if cancer is present.) Together with your doctor, you will decide whether to continue prostate cancer testing, and if so, how often you will be tested.
- If the biopsy results are abnormal: You may have cancer. No two men with prostate cancer are the same, however. When prostate cancer is found at an early stage and has not spread beyond the prostate, the doctor and patient have a choice to make, between one or more active treatments and watchful  ting.
- Many factors affect the decision whether to treat the disease, and also how to treat the disease. These are described on the next page.

**Treatment Issues:
Facts You Should Know
If Prostate Cancer is Found**

When Prostate Cancer is Found, It May Not Always Lead to Active Treatment

One of the major problems in prostate cancer screening is that, once the cancer is found, there is no foolproof way of knowing what the cancer will do.

- Will it grow quickly and spread or will it grow slowly and stay where it is?
- Could it ever cause symptoms?
- Could it cause death?

Here are the facts:

- The **Gleason grade** is one way to measure how fast-growing a cancer could be. However, it is *not* completely accurate.
- Because we can't accurately identify which prostate cancers will grow, it is impossible to know for certain who will benefit from treatment and who will not.
- Due to this uncertainty, most men choose an active treatment.
- As a result, some prostate cancers are treated unnecessarily, meaning that the treatment does not help a man live a longer or healthier life.
- This problem, called overtreatment, is thought to be a particular problem in prostate cancer because prostate cancer often grows slowly. Overtreatment is a problem even for African American men, who are at higher risk for prostate cancer.

As a result of this uncertainty, men and their doctors must decide:

- Whether to risk engaging in watchful waiting when a cancer could become fatal
or
- Whether to risk treating a cancer that may not ever cause any problems.
- **The problem with NOT treating prostate cancer that may be fast growing:**
 - The cancer may spread, making it more difficult to treat the cancer successfully.
 - Treatment options may be limited once the cancer has spread.
- **The problem with treating prostate cancer that may be slow growing:**
 - The side effects of active treatment could make a man's life more difficult than the cancer ever would have.
 - So, the side effects of treatment may be a high a price to pay for treating a slow-growing prostate cancer.

Are some treatments better at saving lives than others?

It's hard to believe, but at this time we don't know whether any particular treatment is more effective than others at reducing deaths due to prostate cancer.

For men with early stage prostate cancer, there are 2 main decisions to make.

1. *Whether* to actively treat the disease

- Some men decide to actively treat the prostate cancer.
- Some men choose to watch it and wait. The patient's prostate cancer is closely watched by performing the PSA test and DRE regularly. Then, the cancer is treated only if and when the prostate cancer shows signs of growing or causes symptoms.

2. *How* to actively treat the disease

If a man decides to treat his prostate cancer, there are a number of treatment options. Active treatments include:

- **Surgery** (radical prostatectomy): Surgery is performed to remove the prostate.
- **External radiation therapy:** Radiation is directed at the prostate. This helps to destroy cancer cells.
- **Internal radiation therapy (brachytherapy):** Surgery is performed to place small radioactive pellets inside or near the cancer. These help to destroy cancer cells.
- **Hormone therapy:** Certain hormones are given or removed. This helps to keep cancer cells from growing.
- **Cryotherapy:** A special probe is placed inside or near the prostate cancer. This helps to freeze and destroy the cancer cells.

When making these decisions, there are several factors to consider:

Many factors affect the treatment decisions men make. To decide whether to treat or how to treat prostate cancer, men and their doctors consider several things:

- A man's age
- The stage of the cancer
- A man's other medical conditions and overall health
- A man's feelings about treatment side effects and how they may impact his life
- What a man feels is best for him and the priorities in his life
- How a man feels about the scientific uncertainty of the effectiveness of treatments
- How a man weighs his length of life vs. his quality of life

Current Treatment Options for *Late Stage* Prostate Cancer

More *advanced* prostate cancers that have spread beyond the prostate can be complex to treat and are often incurable. Patients should discuss with their doctor the best course of action.

Do these active treatments have side effects?

Side effects from prostate cancer treatment depend mainly on 3 things:

- The type of treatment
- A man's age
- A man's overall health

Men who are treated for early-stage prostate cancer may experience the following side effects:

- Pain
- Discomfort
- Impotence (being unable to have and keep an erection)
- Incontinence (being unable to hold urine and feces)

Side effects can vary.

- They can be mild to severe.
- They can be temporary or may last a long time.
- Some can be more easily treated than others.

Your doctor will be able to help.

- When a doctor explains the treatment choices, he or she can discuss the side effects with you and let you know what to expect.
- Also, a doctor may be able to perform surgery or prescribe medicine to relieve some side effects, including impotence.
- Together, you and your doctor will consider many factors in deciding what treatment is best for you.

How long do the side effects of treatment last? It is hard to say.

- Studies have been done to answer that question. But, we still can't say for sure how many men will experience side effects, or how long they will last.
- We just know that men who are treated for early-stage prostate cancer are likely to experience side effects. See page XX for more information on side effects.

Besides treatment, can anything else cause these same problems? Yes.

- **A cancer that is growing:** These problems can be caused by the prostate cancer itself.
- **Men without prostate cancer** can develop these symptoms due to:
 - Getting older
 - Other illnesses

Putting All of This Information to Use:
Steps You Can Take

1. Know the Risk Factors for Prostate Cancer: Think About *Your* Risks

What increases your chances of having prostate cancer?

Based on studies, here's what we know, so far.

Your Age

- The chance of having prostate cancer increases with age, particularly after age 50.
- More than 70% of all prostate cancers are diagnosed in men over 65.

Your Family History

- Men with a father or brother who has had prostate cancer are at greater risk for developing it themselves.
- The younger a man is when he has prostate cancer, the greater the risk for his male family members.

Your Race

- Prostate cancer is more common in African-American men than in white men. The death rate from prostate cancer is also higher for African American men.
- It is less common in Hispanic, Asian, Pacific Islander, and Native American men than in white men. But they do get it.
- Medical experts do not understand the causes of these differences.

These are all things that you have no control over. But knowing this can help you to decide how to best take care of yourself.

Diet

We need to know more about how diet may make a difference in men's risk for prostate cancer.

- Some studies suggest that a diet high in fat, including fried or creamy foods, may increase the risk of prostate cancer. But not all experts agree.
- Researchers are studying several factors that may lower a man's chance of developing the disease, such as:
 - a diet high in fruits, vegetables (tomatoes, in particular), and soy
 - the use of nutritional supplements (e.g., selenium, vitamin E).

2. Learn the Symptoms of Prostate Cancer

There may be no symptoms

Most men who are diagnosed with prostate cancer have NO symptoms.

- So, you can have prostate cancer and not notice any problems.
- This is the potential benefit of undergoing screening: that the screening tests can detect cancer before there are symptoms.

Sometimes, there *are* symptoms

Some symptoms might be a sign of prostate cancer. This is particularly true when the cancer is more advanced.

- The need to urinate frequently, especially at night
- Weak or interrupted urine flow
- Pain or burning feeling while urinating
- The inability to urinate
- Blood in the urine
- Constant pain in the lower back, pelvis, or upper thighs
- Fatigue (extreme tiredness)
- Weight loss (when a man is *not* trying to lose weight)

Sometimes, symptoms may not be due to cancer

Keep in mind, you can have these symptoms and not have cancer:

- They can be caused by *other* prostate problems that are *not* cancer.
- They can be caused by other medical conditions.
- They can also be caused by certain medications.
- Some symptoms (e.g., fatigue) can be caused by aging.

What to do if you do have symptoms

- If you have any of these symptoms, see your doctor.
- Get a diagnosis. Find out what is causing your symptoms.

3. Talk with Your Doctor About Screening: Ask Questions

Talk with your doctor:

Although the information in this booklet will help, it cannot replace the conversations you have with your doctor. Talking with your doctor is perhaps the most important step in making health decisions.

Consider asking these 3 questions:

To decide whether screening is right for you, discuss screening with your doctor and the people important in your life. We have listed some questions you might want to discuss with your doctor.

1. Can you explain why I should consider getting screened for prostate cancer?
Can you also explain why I should consider not getting screened?
2. If I am screened and then diagnosed with prostate cancer, can you tell me about some of the treatments I might want to consider?
3. I have learned that doctors disagree about whether men who do NOT have symptoms should be screened for prostate cancer.
 - Can you tell me your views about this? -
 - Can you also tell me what you would recommend in my particular case?

Plan to ask questions of your own

We have also left space for you to write in your own questions.

4.

5.

6.

Worksheet for Making Your Screening Decision: Decide How You Feel and What is Important to You

Below are issues to think about when making a decision about screening.

- First, read the following sentences and check Yes or No for each one, depending on whether the sentence sounds like you or not.
- Then, look at all the sentences that you checked yes to see whether you lean more toward getting screened or more toward not getting screened.



Does this sound like you?

YES NO

If the statements below sound like you, you may want to get screened.

I am worried about prostate cancer and screening may give me peace of mind.

I am prepared to accept the chance that screening might find prostate cancer that may not have caused me any problems. But, I would still rather know if I have cancer.

Screening will help me feel like I am doing everything I can do for my health.

I accept that screening has not yet been proven to save lives. But, in the future we may find out that it does. So, I think it's better to be "safe than sorry."

If I am diagnosed with prostate cancer, I know that I will need to either be prepared to accept living with untreated cancer, OR be prepared to accept the side effects of treatment, including impotence, incontinence, and bowel problems. But, I feel these problems are the price for the possibility of a longer life.

If the statements below sound like you, you may not want to get screened.

I do not want to risk finding out I have cancer, especially when it may never bother me.

If I do not get screened, I am prepared to accept the possibility that researchers may later find out that screening lowers the chance of dying from prostate cancer.

Screening may give an abnormal result when no cancer is present. It may also give a normal result when cancer is present. I want the test to be more accurate before I use it.

Screening may cause me to have a prostate biopsy that turns out to be unnecessary, if cancer is not found. I want the test to be more accurate before I use it.

Screening has not yet been proven to save lives. If I am diagnosed and treated for prostate cancer, living with the treatment complications (e.g., impotence, incontinence, bowel problems) would be very difficult. Living with these complications would not be worth the possible, but unproven, chance of a longer life.

Adapted from Gattellari, M. & Ward, J.E. (2003).

end box*****

Beyond the Basics:
Statistics and Research Issues

What is the best method for measuring PSA?

Researchers are exploring several different ways of measuring PSA.

PSA velocity

- PSA velocity is based on changes in PSA levels over time.
- A sharp rise in the PSA level raises the suspicion of cancer.

Age-adjusted PSA

- Age is an important factor in increasing PSA levels. For this reason, some doctors use age-adjusted PSA levels to determine when diagnostic tests are needed.
- When age-adjusted PSA levels are used, a different PSA level is defined as normal for different age groups.
- Doctors who use this method generally suggest
 - For men younger than age 50: They should have a PSA level below 2.4 ng/ml.
 - For men in their 70's: They should have a PSA level up to 6.5 ng/ml.
- Doctors do not agree about the accuracy and usefulness of age-adjusted PSA levels.

PSA density

- PSA density considers the relationship of the PSA level to the size of the prostate.
- This means that an elevated PSA might not arouse suspicion if a man has a very enlarged prostate.
- This approach increases the risk that a cancer might be overlooked in a man with an enlarged prostate.
- Therefore, the use of PSA density to interpret PSA results has not been settled.

Free versus attached PSA

- PSA circulates in the blood in 2 forms: free or attached to a protein molecule.
- With benign prostate conditions, there is more free PSA. With prostate cancer, there is more of the attached form of PSA.
- Many doctors use the measure of free PSA to help them interpret a man's PSA level.

These different ways of measuring PSA may make prostate cancer detection more accurate. However, it is important to know that these ways of measuring PSA do not address the basic issue of whether early detection and treatment save lives. Even if we can improve methods of finding prostate cancer, we still do not know whether finding it reduces the number of deaths from it.

Issues Related to Risk of Death from Prostate Cancer

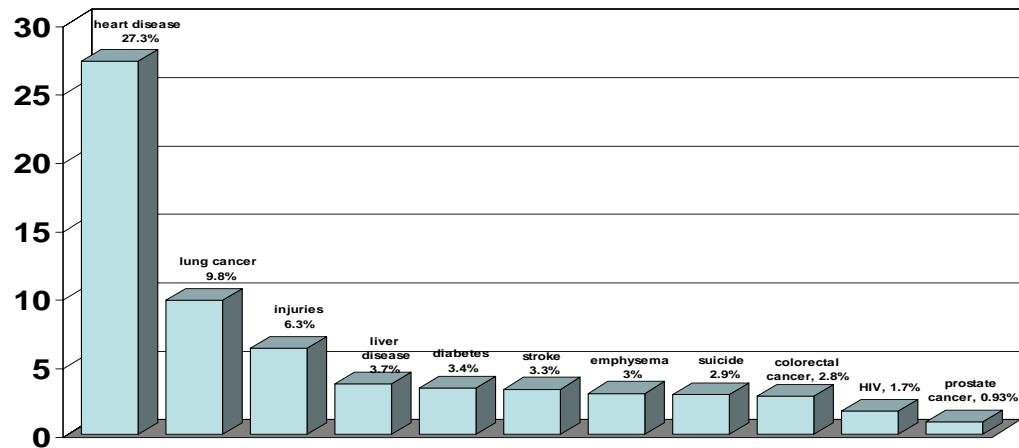
You have a greater chance of dying of something other than prostate cancer

- The two figures on the next page show the top twelve causes of death in two groups:
 - U.S. men who are 45-64 years of age: prostate cancer ranks 12th, behind all other common causes of death.
 - U.S. men who are 65 years of age and older: prostate cancer ranks 5th, behind heart disease, lung cancer, stroke, and emphysema.
 - These graphs show that other diseases often cause death before prostate cancer does. Even though prostate cancer is given a lot of attention in the media and by doctors, there are many other diseases that are more deadly than prostate cancer.
 - As a result, most men with prostate cancer end up dying of illnesses other than prostate cancer. This is why experts sometimes say, "More men die *with* prostate cancer than *of* prostate cancer."

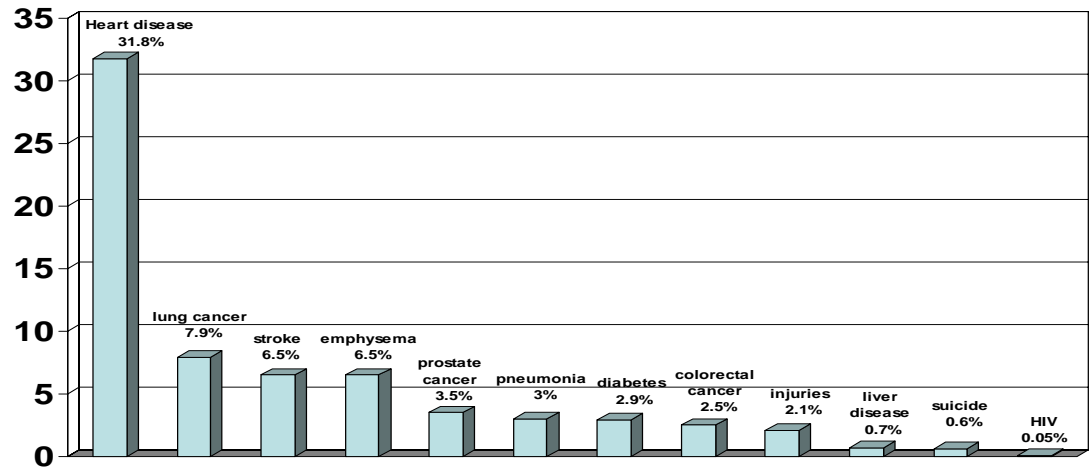
What diseases are most likely to cause death in men?



Causes of death in men ages 45-64

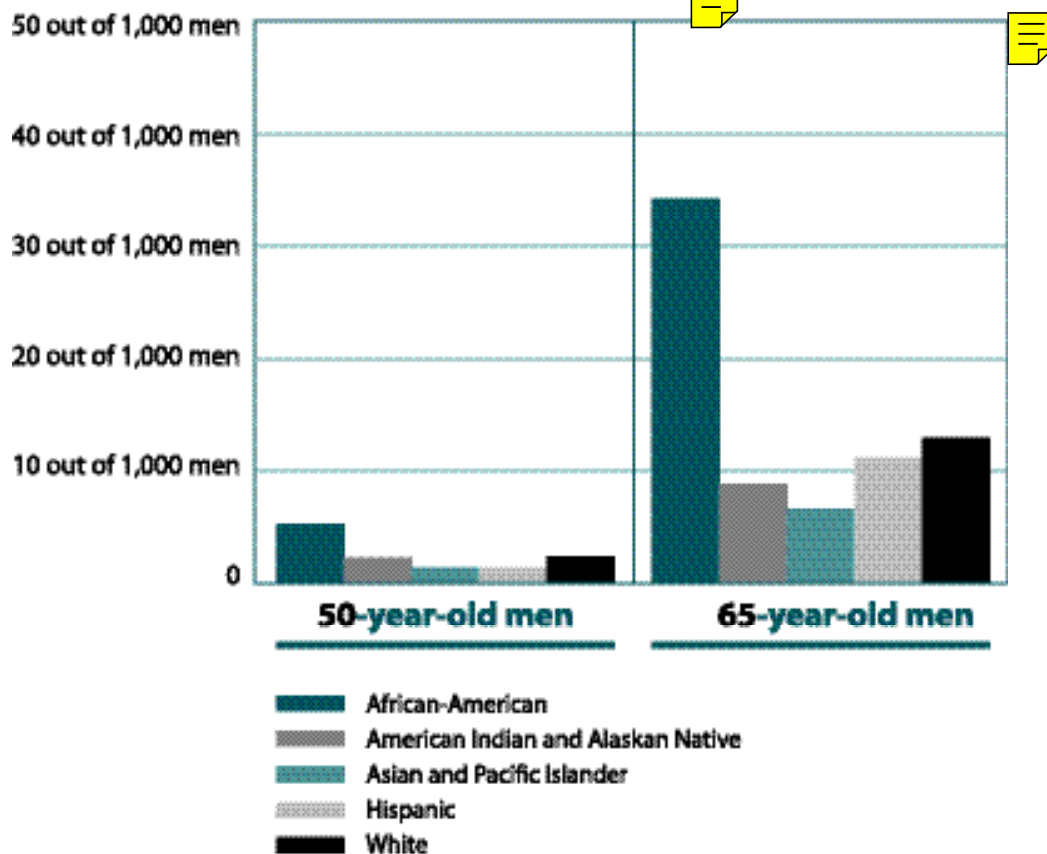


Causes of death in men 65 and older



What are the chances of dying from prostate cancer?

Out of 1,000 men, this chart shows the chance of dying from prostate cancer in the next 15 years — for 50-year-old men and for 65-year-old men.



- The left side of the chart shows that, for a 50 year old man, his chance of dying from prostate cancer in the next 15 years is fairly low (5 or fewer in 1000 men).
- The right side of the chart shows that, for a 65 year old man, the chance of dying from prostate cancer in the next 15 years rises. This is particularly true for African American men.
- Even though your chance of dying from prostate cancer increases with age, it remains relatively low overall. About 3% of all males will die of prostate cancer over their lifetime. Among men who are diagnosed at 50, 3.2% will eventually die of prostate cancer. Among men who are diagnosed at age 65, 3.6% will eventually die of prostate cancer.


Issues Related to Treatment and Disease Outcomes

Choosing active treatment is a particular concern for older men.

- Men over age 75 are more likely than younger men to have other life-threatening health concerns (heart disease and diabetes, among others).
- Because prostate cancer often grows slowly, these other illnesses are more likely than prostate cancer to cause death.
- As a result, older men are less likely to benefit from finding and treating prostate cancer.

More details on side effects of treatments

- The information below shows the percentages of men who continue to experience certain common side effects up to 5 years after they have completed surgical or radiation treatment.
- The wide range of percentages represents the collection of results from different studies.
- We can't say for sure how many men will experience these common side effects, or how long the side effects will last. The main point to understand is that many men do experience these side effects following treatment for prostate cancer.

	Surgery (general or nerve- sparing)	Radiation therapy
Problems with urination	15%-50%	2%-16%
Problems with bowel movements	3%-20%	6%-25%
Problem with sexual function	20%-79%	20%-  b

We show this information to give you an idea of the side effects men may face when they are treated for prostate cancer. However, in the event you are diagnosed with prostate cancer, you and your doctor would need to consider many factors in deciding what treatment is best for you.

Glossary:
Words and Terms You May Want to Know

Glossary

Active treatment: Surgery, external radiation therapy, internal radiation therapy, hormone therapy, or cryotherapy, or a combination of these treatments.

Average-risk:

Benign: Not cancerous.

Benign prostatic hyperplasia (BPH): Enlargement of the prostate. BPH is not cancer, but it can cause some of the same symptoms.

Biopsy: The removal of a sample of tissue, which is then examined under a microscope to check for cancerous changes.

Bladder: The organ that stores urine.

Bowel movement problems: Can include frequent bowel movements, sudden urges to have bowel movements, or not being able to control your bowel movements.

Brachytherapy: Radioactive material sealed in needles, seeds, wires, or catheters is placed directly into or near the tumor. Also called internal radiation, implant radiation, or interstitial radiation therapy.

Cancer: A term for diseases in which abnormal cells divide without control. Cancer cells are able to invade nearby tissues and to spread through the bloodstream to other parts of the body.

Catheterization: A procedure whereby a thin tube (catheter) is inserted into the urethra to drain and empty the bladder.

Clinical Trial/Study or Research Study: A study that involves people and is designed to answer medical questions and to find better ways to prevent or treat disease.

Cryotherapy: Treatment performed with an instrument that freezes and destroys abnormal tissues.

Cystoscopy: Examination of the bladder and urethra using a thin, lighted instrument (called a cystoscope) inserted into the urethra. Tissue samples can be removed and examined under a microscope to find out if disease is present.

Digital rectal examination (DRE): A procedure in which the doctor inserts a gloved, lubricated finger into the rectum to examine the rectum and prostate for anything not normal. Some tumors of the prostate can be felt during this exam.

Early-stage prostate cancer: Cancer that is confined to the prostate and has not spread to other parts of the body.

European Randomized Screening for Prostate Cancer (ERSPC): A major European study that should tell us whether screening for prostate cancer should be a part of routine health care or not. The study is connected with another big study in the U.S. called the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial and involves 8 countries.

External radiation therapy: Radiation therapy that uses a machine to aim high-energy rays at the cancer. Also called external beam radiation.

False negative screening result: When a screening test shows a normal test result when cancer is actually present.

False positive screening result: When a screening test shows an abnormal test result when cancer is actually absent. A prostate biopsy that is normal (not cancerous) means that the screening test was incorrect (i.e., falsely positive).

Family history: Prostate cancer seems to run in some families. Having a father or brother (first degree relatives) with prostate cancer doubles a man's risk of developing this disease. The risk is higher for men who have had several first-degree relatives with the disease or if their relatives were young when the cancer was found.

First degree relative: A relative in your immediate family: For prostate cancer this means father, a brother, or a son. Cousins, aunts, uncles, grandparents are 'second degree' relatives.

Finasteride: A drug used to reduce the amount of male hormone (testosterone) produced by the body.

Gland: An organ that produces and releases one or more substances used by various parts of the body.

Hormone therapy: Treatment of cancer by removing, blocking, or adding hormones.

Impotence: Not being able to have an erection that is adequate for sexual intercourse.

Incontinence: Not being able to hold or control the flow of urine.

Informed decision: A decision that is made after all of the information and possible outcomes have been examined.

Internal radiation therapy: Radiation therapy that is given internally. This is done by placing radioactive material that is sealed in needles, seeds, wires, or catheters directly

into or near the tumor. Also called implant radiation, interstitial radiation, or brachytherapy.

Latent prostate cancer: See “Overdiagnosis”

Overdiagnosis: Detection of cancer that would otherwise not have been noticed in the patient’s lifetime. Such cancers, known as latent tumors, grow slowly or not at all.

Prostate cancer: A disease in which prostate cells grow out of control. Spurred by changes in the genes, the glandular cells of the prostate multiply abnormally.

Prostate gland: A male sex gland. The prostate produces fluid that forms part of semen that carries sperm.

Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial: A large-scale National Cancer Institute sponsored study to determine if certain tests will reduce the number of deaths from prostate, lung, colorectal, and ovarian cancers.

Prostate specific antigen (PSA): A protein produced by cells of the prostate gland. PSA circulates in the bloodstream and can be measured with a simple blood test. PSA levels rise in the blood of some men who have prostate enlargement, inflammation, infection, or cancer.

Prostatectomy: An operation to remove part or all of the prostate. Radical (or total) prostatectomy is the removal of the entire prostate and some of the tissue around it.

Prostatitis: Inflammation of the prostate. Prostatitis is not cancer.

Rectum: The lower part (last 8 to 10 inches) of the large intestine. The rectum stores solid waste until it leaves the body through the anus.

Risk factor: Something that increases a person’s chance of developing a disease.

Screening: Checking for signs of disease in a person who has no symptoms. For example, screening measures for prostate cancer include digital rectal examination (DRE) and the PSA blood test. Screening may refer to programs that are designed to test many people.

Sexual functioning problems: Can include not being able to get an erection, not being able to have intercourse, or being unhappy with the erections you can get.

Shared Decision-Making: The process of a patient working together with his health care providers to make decisions about screening and/or treatment.

Side effects: Undesirable results that may accompany treatment. The potential side effects of prostate cancer treatment include incontinence, impotence, and bowel problems.

Surgery: A procedure to remove or repair a part of the body or to find out if disease is present.

Symptom: Effect of disease as experienced by the patient. Pain, for example, is a symptom.

Transrectal Ultrasound (TRUS): The use of sound waves to produce an image of the prostate. The sound waves are emitted by an instrument inserted into the rectum. As the waves bounce off the prostate, they create a pattern that is converted by a computer into a picture. TRUS is used to detect abnormal prostate growth and to guide a biopsy of the abnormal prostate area.

Tumor: Abnormal growth of tissue. Tumors can be malignant (cancerous) or benign (not cancerous).

Urethra: The tube that extends from the bladder to the tip of the penis. It carries urine from the bladder and, during ejaculation, semen from the prostate gland, out through the penis.

Urination problems: Can include frequent or painful urination, sudden urges to urinate, bloody urine, or not being able to control urination (i.e., leaking urine).

Urologist: A doctor (surgeon) who specializes in disorders of the urinary system and the male reproductive system.

Watchful Waiting: Following the patient closely and postponing aggressive therapy unless symptoms or other signs of disease progress. Watchful waiting can be a choice for treating both an enlarged prostate and early-stage prostate cancer.

Definitions adapted from Understanding Prostate Changes: A Health Guide for All Men, National Cancer Institute, September 1999, NIH Publication No. 98-4303; What You Need to Know About Prostate Cancer, National Cancer Institute, September 2000, NIH Publication No. 00-1576; and the American Cancer Society's cancer glossary at www.cancer.org.

Resources and References: Where to Find More Information

National ganizations

For more information on prostate cancer screening, treatments, and studies, please contact the organizations below. Although these organizations may either recommend for or against screening, all recommend shared decision making with your doctor.

American Academy of Family Physicians 800-274-2237 www.aafp.org

American Cancer Society 800-227-2345 www.cancer.org

American College of Physicians 800-338-2746 www.acponline.org

American College of Preventive Medicine 202-466-2044 www.acpm.org

American Foundation of Urologic Disease 1-866-746-4282 www.afud.org

American Medical Association 1-800-621-8335 www.ama-assn.org

American Urological Association 866-746-4282 www.auanet.org

Centers for Disease Control and Prevention 800-311-3435 www.cdc.gov

European Randomized Screening for

Prostate Cancer Trial (Web site only) www.erspc.org

National Cancer Institute (NCI) 800-422-6237 www.cancer.gov

National Medical Association 202-347-1895 www.nmanet.org

National Prostate Cancer Coalition 888-245-9455 www.pcacoalition.org

NCI's Prostate Cancer Outcomes Study 800-422-6237
www.cancer.gov/newscenter/pcos

NCI's Prostate, Lung, Colorectal, and Ovarian

Cancer Screening Trial 800-422-6237 www.cancer.gov/prevention/plco

Oncolink (Web site only) www.oncolink.upenn.edu

Prostate Cancer Education Council 866-477-6788 www.pcaw.com

U.S. Preventive Services Task Force (Web site only)

www.ahrq.gov/clinic/uspstfix.htm

US TOO Cancer Education and Support 800-808-7866 www.ustoo.com

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Schwartz, K., Bunner, S., Bearer, R., Severson, R.K. (2002). Complications from treatment for prostate carcinoma among men in the Detroit area. *Cancer*, 95 (1): 82-89.

Steineck, G., Helgesen, F., Adolfsson, J., Dickman, P.W., Johansson, J., Norlen, B.J., Holmberg, L. (2002). Quality of life after radical prostatectomy or watchful waiting. *New England Journal of Medicine*, 347 (11): 790-796.

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Inside **Back Cover**

This information was developed by researchers at Georgetown University (Grant # XXX), with content adapted from Prostate Cancer Screening: Making an Informed Decision (1 R01 CA 098967-01) and from Prostate Cancer Screening: A Decision Guide, published by the Centers for Disease Control and Prevention (CDC). Additional information was obtained from published research studies.

Information in this booklet is accurate at the time of printing (XXX).

Research currently underway may change its contents.

back cover*****

Lombardi Comprehensive Cancer Center

Georgetown University

Medical Center

Washington Hospital Center

Internet-Based Education for Prostate Cancer Screening Feasibility Study Outcomes Table (N=99)

Outcomes	GU (N=50)	WHC (N=49)	TOTAL (N=99)
Do you use a computer at home?*			
Yes (N=67)	92%	43%	68%
No (N=32)	8%	57%	32%
What type of computer do you have at home?			
PC (N=54)	78.3%	85.7%	80.6%
MAC (N=3)	4.3%	4.8%	4.5%
Other (N=7)	15.2%	.0%	10.4%
Not Sure (N=3)	2.2%	9.5%	4.5%
How old is your computer at home?			
<2 years old (N=34)	47.8%	57.1%	50.7%
2 to 5 years old (N=28)	47.8%	28.6%	41.8%
>5 years old (N=5)	4.3%	14.3%	7.5%
On your computer at home do you have a CD-Rom?			
Yes (N=63)	97.8%	85.7%	94%
No (N=3)	2.2%	9.5%	4.5%
Not Sure (N=1)	.0%	4.8%	1.5%
On your computer at home do you have a USB port?			
Yes (N=52)	82.6%	66.7%	77.6%
No (N=13)	15.2%	28.6%	19.4%
Not Sure (N=2)	2.2%	4.8%	3%
Do you have an internet connection for your home computer?			
Yes (N=67)	100%	100%	100%
No (N=0)	0%	0%	0%
How do you connect to the internet on your home computer?*			
Dial-up (N=15)	13%	42.9%	22.4%
High-speed (N=51)	84.8%	57.1%	76.1%
Other (N=1)	2.2%	0%	1.5%
Not Sure (N=0)	0%	0%	0%
How often do you use the internet at home?			
Never/Rarely (N=1)	0%	4.8%	1.5%
A few times per year (N=0)	0%	0%	0%
A few times per month (N=6)	4.3%	19%	9%
Once per week (N=5)	6.5%	9.5%	7.5%
Several times per week (N=19)	34.8%	14.3%	28.4%
Daily (N=36)	54.3%	52.4%	53.7%

Outcomes	GU (N=50)	WHC (N=49)	TOTAL (N=99)
Do you use a computer at work?*			
Yes (N=59)	86%	32.7%	59.6%
No (N=40)	14%	67.3%	40.4%
Do you use a computer at work?++			
Yes (N=5)	25%	14.3%	15.6%
No (N=27)	75%	85.7%	84.4%
Can you use your computer at work for personal use?			
Yes (N=41)	67.4%	75%	69.5%
No (N=18)	32.6%	25%	30.5%
Do you have an internet connection at work?			
Yes (N=42)	100%	100%	100%
No (N=0)	0%	0%	0%
Can you use the internet for personal use at work?			
Yes (N=41)	100%	92.3%	97.6%
No (N=1)	0%	7.7%	2.4%
How do you connect to the internet on your work computer?			
Dial-up (N=0)	0%	0%	0%
High-speed (N=39)	96.6%	91.7%	95.1%
Other (N=1)	3.4%	0%	2.4%
Not Sure (N=1)	0%	8.3%	2.4%
How often do you use the internet at work?			
Never/Rarely (N=0)	0%	0%	0%
A few times per year (N=0)	0%	0%	0%
A few times per month (N=0)	0%	0%	0%
Once per week (N=0)	0%	0%	0%
Several times per week (N=2)	3.4%	8.3%	4.9%
Daily (N=39)	96.6%	91.7%	95.1%
What type of computer do you have at work?			
PC (N=38)	96.6%	83.3%	92.7%
MAC (N=0)	0%	0%	0%
Other (N=1)	3.4%	0%	2.4%
Not Sure (N=2)	0%	16.7%	4.9%
On your computer at work do you have a CD-Rom?			
Yes (N=35)	93.1%	66.7%	85.4%
No (N=5)	6.9%	25%	12.2%
Not Sure (N=1)	0%	8.3%	2.4%

Outcomes	GU (N=50)	WHC (N=49)	TOTAL (N=99)
On your computer at work do you have a USB port?			
Yes (N=35)	86.2%	83.3%	85.4%
No (N=5)	13.8%	8.3%	12.2%
Not Sure (N=1)	0%	8.3%	2.4%
How old is your computer at work?			
<2 years old (N=23)	62.1%	41.7%	56.1%
2 to 5 years old (N=15)	34.5%	41.7%	36.6%
>5 years old (N=3)	3.4%	16.7%	7.3%
Would you be willing to go to another location if no access to high-speed internet at home/work?+			
Yes (N=16)	33.3%	45.2%	43.2%
No (N=14)	33.3%	38.7%	37.8%
Not Sure (N=7)	33.3%	16.1%	18.9%
If you are not comfortable accessing the internet on your own, would you ask a friend/family to help you use our PCa website?			
Yes (N=43)	58.1%	71.7%	65.2%
No (N=15)	25.8%	20%	22.7%
Not Sure (N=8)	16.1%	8.6%	12.1%
Would you prefer to receive health-related information on the internet or booklet?*			
Internet (N=45)	72.1%	31.1%	51.1%
Booklet (N=43)	27.9%	68.9%	48.9%
Why are you here today?			
Check-up (N=62)	70%	56.3%	63.3%
Illness (N=11)	16%	6.3%	11.2%
Bring a friend/relative (N=20)	14%	27.1%	20.4%
Blood test/Lab work (N=4)	4%	4.2%	4.1%
Other (N=8)	6%	10.4%	8.2%
If you are here today to bring a friend/relative are you also a patient in this clinic?			
Yes (N=5)	2%	8.3%	5.1%
No (N=17)	12%	22.9%	17.3%
N/A (N=76)	86%	68.8%	77.6%

Outcomes	GU (N=50)	WHC (N=49)	TOTAL (N=99)
How old are you? M (SD)	53.85 (7.54)	55.24 (7.30)	54.55 (7.42)
What is your marital status?			
Never Married (N=19)	12%	27.7%	19.6%
Married (N=53)	78%	29.8%	54.6%
Living as married (N=4)	2%	6.4%	4.1%
Separated/Divorced (N=20)	8%	34%	20.6%
Widowed (N=1)	0%	2.1%	1%
How far did you go in school?*			
<HS (N=4)	2%	6.1%	4%
HS grad or GED (N=21)	8%	34.7%	21.2%
Vocational/trade school (N=6)	4%	8.2%	6.1%
Some college (N=13)	6%	20.4%	13.1%
College grad (N=18)	26%	10.2%	18.2%
Some graduate school (N=5)	4%	6.1%	5.1%
Graduate/professional degree (N=32)	50%	14.3%	32.3%
To what racial/ethnic group do you belong to?*			
Black/AA (N=48)	28%	75.6%	50.5%
Hispanic/Latino (N=4)	6%	2.2%	4.2%
Asian/Pacific Islander (N=3)	6%	0%	3.2%
Native American (N=1)	2%	0%	1.1%
Caribbean/West Indian (N=1)	0%	2.2%	1.1%
White (N=35)	52%	20%	36.8%
Other (N=3)	6%	0%	3.2%
If you eat the entire container how many calories will you eat?*			
Correct (N=45)	68%	22.4%	45.5%
Incorrect (N=54)	32%	70.4%	54.5%
If you are allowed to eat 60g of carb. How much ice cream could you have?*			
Correct (N=62)	84%	40.8%	62.6%
Incorrect (N=37)	16%	59.2%	37.4%

Outcomes	GU (N=50)	WHC (N=49)	TOTAL (N=99)
Your doc advises you to reduce the amt of sat fat in your diet. You usually eat 42g of sat fat which includes 1 serving of ice cream, if you stop eating ice cream how many grams of sat fat would you be consuming?*			
Correct (N=35)	52%	18.4%	35.4%
Incorrect (N=64)	48%	81.6%	64.6%
If you usually eat 2,500 cal in a day, what % of your daily value of cal will you be eating if you eat 1 serving?*			
Correct (N=54)	74%	34.7%	54.5%
Incorrect (N=45)	26%	65.3%	45.5%
Pretend you are allergic to the following substances, is it safe for you to eat this ice cream?*			
Correct (N=49)	60%	38.8%	49.5%
Incorrect (N=50)	40%	61.2%	50.5%
Why not?*			
Correct (N=39)	54%	24.5%	39.4%
Incorrect (N=60)	46%	75.5%	60.6%
New Vital Scale Total Score			
M (SD)	3.90 (2.03)	1.91 (1.84)	2.91 (2.17)

*P<.05

+ Limited to those respondents that did not have a high speed internet connection at home or at work.

++ Limited to those respondents that did not have a computer at home.

4/21/06

Internet and Print-Based Education for Prostate Cancer Screening
Baseline Interview T0

Verbal Informed Consent (randomized trial)

ID: _____ Date of Accrual _____ Interviewer: _____

Time started: _____ Time Ended: _____ Total Time: _____

Hello, my name is _____, and I am calling from Georgetown University. May I please speak with Mr. _____ (participant's name)?

IF NOT AVAILABLE/BUSY, ASK:

What would be the best time to call back? Date _____ Time _____ a.m./p.m.

I am calling to invite you to participate in a research study here at Georgetown University/Washington Hospital Center. I am a member of a research team that is conducting this study in collaboration with Dr. Mary Fishman/Dr. Carmella Cole and the medical staff in the Department of Medicine. We recently mailed you a letter describing our study, which has to do with teaching men about prostate cancer screening. Do you have a few minutes now so I can tell you about the study and to see if you are interested in participating? [If yes, proceed to paragraph below; if no, ask when it would be best to call back.]

This research was approved by the MedStar Research Institute/Georgetown University Medical Center Institutional Review Board. This research is sponsored by the Department of Defense and the National Cancer Institute. The purpose of this study is to assess whether men are willing and able to use the Internet to receive educational information about prostate cancer screening. This research is being done to develop ways to educate large numbers of men about the pros and cons of prostate cancer screening. Do you have any questions at this point? [If yes, answer factually; if no, proceed to next item.]

Let me see if you are eligible: Are you between the ages of 45 and 70? _____ y _____ n
Do you have a history of prostate cancer? _____ y _____ n
[If eligible, continue; if ineligible, go to early close for age or prostate cancer.]

Early Close – AGE: Because our study is specifically designed for men who are between the ages of 45-70, this study will not be relevant for you. Thank you for your time and willingness to answer these questions. Please do not hesitate to call us if we can be of any assistance to you at (202) 687-6858.

Early Close – PROSTATE CANCER:
Because our study is specifically for men who have not had a prior diagnosis of prostate cancer, this study will not be relevant for you. If you are interested in participating in other studies specifically designed for cancer patients, please call 1-800-4-CANCER. Thank you for your time and willingness to answer these questions. Please do not hesitate to call us if we can be of any assistance to you at 202-687-6858.

Men who agree to participate in this research project will look at the educational materials and tell us what they think about them. We will also ask men about their attitudes, behaviors, and beliefs about prostate cancer. Men who agree to be in this research project will first have a telephone interview to answer questions about their attitudes, behaviors, and beliefs about prostate cancer. This 15-minute interview will be set for a time that is best for each man. After the interview, each man will be assigned to one of the three groups. There is no way of knowing, beforehand, which group you will be in. Each man has the same chance of being in one of the three groups.

Group 1 Men who receive a printed booklet about prostate cancer screening, including risk factors,

epidemiology, a discussion of the controversy surrounding prostate cancer screening, a glossary of terms, and a 'decision aid,' a worksheet designed to help men understand what the best personal decision is regarding screening.

- Group 2 Men who receive instructions on how to access a website about prostate cancer screening. The website will contain information similar to the booklet described above.
- Group 3 Men who receive usual care, which means they will not receive either of the experimental educational materials described above.

The second telephone interview will occur within 4 weeks of the first interview. The final interview will be conducted about one year later.

In summary, if you agree to participate, you will be asked to complete 3 telephone interviews over the course of 1 year; you will be assigned by chance to 1 of the 3 groups, and to allow us access to the results of your screening tests. You will not be asked to pay for anything in this research project. It will, however, require some of your time to look through the materials and to be interviewed three times by phone. The total time you will devote to this project is approximately two hours over the course of one year. You are volunteering your time for this project. Because we know your time has value and because we are grateful for it, we will send you \$10 when you complete the second telephone interview. There is no secondary payment for the final interview. We will also hold a lottery, to be paid out following completion of the second telephone interview and again at the one-year follow-up interview. At both points, participants will be eligible to win \$100 (30 men) and \$200 (20 men). Do you have any questions at this time?

Your other option is to not participate in this study. If you choose not to join this study, it will not affect your present or future medical care at Georgetown University Medical Center/Washington Hospital Center.

Now I would like to tell you about the possible benefits and possible risks of participation.

We do not guarantee that men who participate will receive a direct benefit. However, they may benefit from this study by learning more about prostate cancer screening. Men will be assisting the medical community and other men in learning how men make screening decisions. Taking part in the study is entirely voluntary, you may withdraw from the study at any time without any of the benefits you would have received normally being limited or taken away. If you choose to withdraw from the study at any time, you may contact Dr. Kathryn Taylor at (202) 687-0649.

The risks of participating in this research study are minimal. Some patients may find the interview or the factual information about prostate cancer distressing. Another possible risk involved in this study is potential embarrassment over discussing personal health concerns. We will make every effort to minimize this possibility. Men who agree to participate have the right to refuse to answer specific questions that they feel are too personal or that they simply do not wish to answer, but can still participate in the study if they so choose. Although there is a risk of breach of confidentiality inherent in any research study, the information we obtain will not have the participant's name on it. It will have a code number that is separated from names and other identifying information. Only the group level data will be reported in any presentations or published papers.

It is extremely unlikely that you will be harmed as a result of participation in this study. We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in the study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds are available from Georgetown University, Georgetown University Hospital, Washington Hospital Center, or their affiliates, the District of Columbia government or the federal government to compensate you for a study-related injury or illness.

Organizations that may request, inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as the Department of Defense, National Cancer Institute, MedStar Research Institute, Georgetown University, and the Georgetown University Institutional Review Board (IRB). Representatives of the U.S. Army Medical Research Medical Command are also eligible to review research records as a part of their responsibility to protect human subjects in research.

For questions about the study or to withdraw from the study, call Kathryn Taylor, Ph.D. at 202-687-0649. For questions about your rights as a research participant, contact the MedStar Research Institute-Georgetown University Oncology Institutional Review Board at: (202) 687-1506.

Does this sound like something in which you would be interested in participating? ☐yes ☐no

IF NO: May I ask why you are not interested in participating?

☐too busy ☐not interested in topic ☐questions too personal ☐other:

IF YES: Great, I am glad you are interested. This interview will take 15 minutes and will ask questions regarding your background, health history, prostate cancer knowledge, decisional preferences, and quality of life. Would it be possible for us to do that interview now?

(If now is not a good time, when is a good time to call back? _____)

PROSTATE CANCER SCREENING HISTORY

First, I would like to find out about your history of prostate cancer screening.

1. Have you ever had an examination for prostate cancer in the past? ☐Yes ☐No (Skip to next section, "Personal history of cancer")

(Note: A PSA is where a health professional draws blood from your arm and tests it for a protein that is made by the prostate gland. A DRE, or digital rectal exam is when a health professional inserts a gloved finger into the rectum and gently presses on the prostate to feel for lumps.)

2. Do you know the approximate date of your most recent examination for prostate cancer?

____/____/____

If date is not known, was it: In the last 12 months? ☐Yes ☐No

In the last 2 years? ☐Yes ☐No

In the last 5 years? ☐Yes ☐No

3. Was the prostate exam done because you were experiencing any prostate-related symptoms (e.g., urinary control, frequent urination, pain)? ☐Yes ☐No ☐Don't Know
4. Have you ever had an abnormal exam in the past (meaning that your doctor thought there was something that needed to be checked out further)? ☐Yes ☐No [Skip to #6] ☐Don't Know
5. [IF YES] Have you had a prostate biopsy previously? ☐Yes ☐No ☐Don't Know

[IF YES] What the result of the biopsy? ☐normal, no evidence of cancer

☐abnormal, diagnosis of prostate cancer [Early close]

☐abnormal, other: _____

6. How often do you get screened for prostate cancer? [Don't read]

☐every 3-6 months ☐less often

☐annually ☐don't know

☐every 2 yrs

7. Approximately how many times would you say you have been screened for prostate cancer in your lifetime? (This would include the PSA and/or DRE)

☐0 ☐1-2 ☐3-4 ☐5-10 ☐11+

8. Would you say that you are usually screened by your own physician or in a free screening program like this one? ☐Physician ☐Free screening program

9. Have you ever had a discussion with a doctor or other health professional about prostate cancer screening? ☐yes ☐no If YES, what did he or she recommend that you do?

☐get screened ☐do not get screened ☐wait to get screened ☐make up my own mind

10. What is your scheduled date of screening? ____/____/____

11. What are the most important reasons that led you to register for screening? [Don't read list – just check]

- a. because a health professional (doctor, nurse) recommended that you participate ___yes ___no
- b. because your wife/partner recommended you participate ___yes ___no
- c. because you have a family history of prostate cancer ___yes ___no
- d. because you have a friend or acquaintance who has been diagnosed w/ prostate cancer ___yes ___no
- e. because you are having symptoms that may be related to prostate cancer ___yes ___no
- f. because you want peace of mind about prostate cancer ___yes ___no
- g. because of the possibility of obtaining free prostate cancer screening ___yes ___no
- h. because you want to make a contribution to medical science by participating in a study ___yes ___no
- i. because you are worried about prostate cancer ___yes ___no
- j. because of the reputation of Georgetown University ___yes ___no

PERSONAL HISTORY OF CANCER

Earlier I asked you about whether you had ever been diagnosed with prostate cancer. Now I would like to ask whether you have ever been diagnosed with any other type of cancer.

_____ Yes _____ No _____ Not Sure

If YES: What type:

(Bladder, Colon, Head/Neck, Lung, Skin, Stomach, Other)

Year diagnosed:

FAMILY HISTORY OF PROSTATE CANCER

Now I would like to ask a few questions about your family history of prostate cancer.

Have any of your blood relatives ever been diagnosed with prostate cancer? ___ Yes ___ No ___ DK

[IF NO: Go to next section.]

[IF YES: See list below and mark accordingly.]

Verify blood relatives (e.g., not brother-in-law)

1 = Father

2 = Older brother

3 = Younger brother

4 = Son

5 = Grandfather

6 = Uncle

Who? _____ How old was he when he was diagnosed? _____

Who? _____ How old was he when he was diagnosed? _____

Who? _____ How old was he when he was diagnosed? _____

OTHER ILLNESSES

Have you ever been diagnosed with any major illnesses?

_____ Yes _____ NO

If YES (Do not read list, just check off the illnesses that apply)

- ☐ Heart Disease
- ☐ High Blood Pressure
- ☐ Diabetes
- ☐ Glaucoma
- ☐ Chronic Obstructive Pulmonary Disease (COPD)
- ☐ Cerebrovascular Disease (CVD)
- ☐ Liver Disease
- ☐ Paralysis/Plegia
- ☐ Asthma/Allergies
- ☐ Arthritis
- ☐ Other, please specify: _____

DECISIONAL CONFLICT SCALE

Short Form

Now I will read a list of statements about your decision to be screened. These things may or may not apply to you. You can answer yes or no to each question.

- | | | | |
|---|----|-----|--------|
| 1. Are you clear about which choice is best for you with regard to screening or not being screened? | No | Yes | Unsure |
| 2. Do you feel sure about your decision? | No | Yes | Unsure |
| 3. Do you know which options are available to you? | No | Yes | Unsure |
| 4. Do you know the advantages of getting screened vs. not getting screened? | No | Yes | Unsure |
| 5. Do you know the disadvantages of each option? | No | Yes | Unsure |
| 6. Are you clear about which of the advantages are most important to you? | No | Yes | Unsure |
| 7. Are you clear about which of the disadvantages are most important to you? | No | Yes | Unsure |
| 8. Do you have enough support from others in order to make a decision? | No | Yes | Unsure |
| 9. Are you making a decision without any pressure from others? | No | Yes | Unsure |
| 10. Do you have enough advice to make a decision? | No | Yes | Unsure |

KNOWLEDGE OF PROSTATE CANCER

Please rate each statement as True (T) or False (F) or Don't Know (DK).

- | | | | |
|--|---|---|----|
| 1. Men who have prostate cancer almost always have | F | T | DK |
|--|---|---|----|

symptoms of the disease. *[indolent nature]*

2. A man's PSA blood test can be normal even if he has prostate cancer. *[false negative]* F T DK
3. Although the PSA test helps to detect prostate cancer early, F doctors cannot say for certain that detecting prostate cancer earlier helps to save lives. *[early det]* T DK
4. Doctors cannot say for certain that treating early stage prostate cancer helps to save lives. *[tx/survival]* F T DK
5. Doctors disagree about whether screening is necessary for men who do not have symptoms of prostate cancer. *[benefit of mass screening]* F T DK
6. When a man gets an abnormal result from the blood test or rectal exam, no further tests are necessary to diagnose prostate cancer. *[need for further tests]* F T DK
7. Prostate cancer appears to run in families. *[fh]* F T DK
8. White men are at greater risk for getting prostate cancer compared to black men. *(race as a risk factor)* F T DK
9. A high fat diet has been linked to prostate cancer. *(diet as a risk factor)* F T DK
10. One of the symptoms of prostate cancer has to do with difficulty urinating, which can include having a weak stream and urges to urinate. *(symptoms)* F T DK
11. Younger men are more likely to have prostate cancer than older men. *(age as a risk factor)* F T DK
12. A prostate cancer test that is abnormal almost always means that prostate cancer is present. *[false positives]* F T DK
13. Some experts may suggest that some men with early-stage prostate cancer not receive any treatment for it. F T DK
14. In general, doctors believe that older men are more likely to benefit from treatment for prostate cancer compared to younger men. F T DK
15. Most men with early-stage prostate cancer who do not get treatment will usually die from their disease. F T DK
16. All experts agree that compared to watchful waiting, treating early-stage prostate cancer will help men live longer. F T DK

SATISFACTION WITH DECISION (Holmes-Rovner Scale)

You have registered for prostate cancer screening. Answer the following questions about your decision. Please indicate to what extent each statement is true for you AT THIS TIME.

Use the following scale to answer the questions:

- 1 = Strongly Disagree
- 2 = Disagree
- 3 = Neither Agree or Disagree
- 4 = Agree
- 5 = Strongly Agree

- ___ 1. I am satisfied that I am adequately informed about the issues important to my decision to get screened.
- ___ 2. The decision to get screened was the best decision possible for me personally.
- ___ 3. I am satisfied that my decision to be screened was consistent with my personal values.
- ___ 4. I expect to successfully carry out (or continue to carry out) the decision I made.
- ___ 5. I am satisfied that this was my decision to make.
(In other words, nobody forced me to make one decision or the other.)
- ___ 6. I am satisfied with my decision to be screened.

SF-12

This next set of questions asks for your views about your health.

1. In general, would you say your health is: ___ Excellent ___ Very good ___ Good ___ Fair ___ Poor
(1) (2) (3) (4) (5)

The following items are about activities you might do during a typical day.

- | | Yes, Limited
A Lot | Yes, Limited
A Little | No, Not
Limited At All |
|--|-----------------------|--------------------------|---------------------------|
| 2. Does your health now limit you in terms of moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf? | 1 | 2 | 3 |
| 3. Does your health limit you in terms of climbing several flights of stairs? | 1 | 2 | 3 |
| 4. During the past 4 weeks, have any problems with your physical health resulted in your accomplishing less than you would like? | Yes (1) | No (0) | |
| 5. During the past 4 weeks, have any problems with your physical health limited you in the kind of work or other activities that you do? | Yes (1) | No (0) | |
| 6. During the past 4 weeks, have any emotional problems such as depression or anxiety resulted in your accomplishing less than you would like? | Yes (1) | No (0) | |

7. During the past 4 weeks, have any emotional problems resulted in your not being able to do your work or other activities as carefully as usual?

Yes (1) No (0)

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and chores around the house)?

Not at all A little bit Moderately Quite a bit Extremely
(0) (1) (2) (3) (4)

These next three questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks. . .

	All	Most	A Good Bit	Some	Little	None
*9. Have you felt calm and peaceful?	1	2	3	4	5	6
10. Did you have a lot of energy?	1	2	3	4	5	6
*11. Have you felt downhearted and blue?	1	2	3	4	5	6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

___All of the time ___ Most of the time ___Some of the time ___A little of the time ___None of the time

PROS AND CONS OF SCREENING

(Items are modified from Rakowski et al, and others are from Hamm protocol). There are 7 pros and 8 cons.

I am going to read a list of statements that people have given for getting prostate cancer screening and for not getting prostate cancer screening. Please listen to each statement and tell me whether you think it is not at all important, somewhat important, or very important to your decision about screening. After reading first item, say 'Would you say that this is not at all important, somewhat important, or very important to your decision about whether to get screened.

	Not at all important	Somewhat important	Very important
1. People who are close to me will be reassured if I am screened for prostate cancer. (pro)			
2. It is embarrassing and/or uncomfortable for me to be screened for prostate cancer. (con)			
3. Prostate cancer screening will give me peace of mind about my health. (pro)			
4. I may get an abnormal screening result that turns out not to be cancer. (con)			
5. I may have more treatment options if screening finds prostate cancer early. (pro)			
6. I do not have the insurance to cover prostate cancer screening follow-up tests and treatment.(con)			
7. I do not want to regret not getting screened. (pro)			
8. Getting screened doesn't guarantee that I am safe from prostate cancer, because tests can miss cancer cells in the prostate. (con)			
9. Prostate cancer screening can find cancer at a point when it is more likely to be cured. (pro)			
10. If prostate cancer screening finds something, then whatever is there may be too far along to do anything about it. (con)			
11. Being screened for prostate cancer could help me live longer. (pro)			
12. I have other health problems that worry me more than prostate cancer. (con)			
13. Screening helps me to feel like I am doing everything I can for my health. (pro)			
14. I worry that if I have prostate cancer screening, I will need a biopsy or an operation. (con)			
15. If I am diagnosed with prostate cancer, I am worried that I will experience side effects from prostate cancer treatment. (con)			

DEGNER CONTROL PREFERENCE SCALE

Overall, how do you prefer to make your prostate cancer screening decisions? Would you say...

- ___ a. I prefer to leave all decisions regarding screening to my doctor.
- ___ b. I prefer that my doctor make the final decision about screening, but seriously consider my opinion.
- ___ c. I prefer that my doctor and I share responsibility for deciding about screening.
- ___ d. I prefer to make the final decision about screening, after seriously considering my doctor's opinion.
- ___ e. I prefer to make the decision about screening.

IMPACT OF EVENTS SCALE (IES)

I am going to read a list of comments made by people about stressful life events. Please indicate how frequently each item was true for you during the past seven (7) days, for prostate cancer, using the following scale: 1 = Not at all; 2 = Rarely; 3 = Sometimes; 4 = Often

- ___ 1. I thought about prostate cancer when I didn't mean to.
- ___ 2. I had trouble falling asleep or staying asleep, because of pictures or thoughts about prostate cancer that came into my mind.
- ___ 3. I had dreams about prostate cancer.
- ___ 4. I had waves of strong feelings about prostate cancer.
- ___ 5. Pictures about prostate cancer popped into my mind.
- ___ 6. Other things kept making me think about prostate cancer.
- ___ 7. Any reminder brought up feelings about prostate cancer.

TRUST ITEMS

- 1. Overall, how much do you trust your doctor(s) to do what is best for you and your health?
___ not at all ___ a little bit ___ somewhat ___ very much ___ completely
- 2. Overall, how much do you trust the healthcare system to do what is best for you and your health?
___ not at all ___ a little bit ___ somewhat ___ very much ___ completely

EUROQOL

Now I would like for you to think about how good or bad your health is, on a 100 point scale. Zero is the equivalent of the worst health you can imagine, all the way up to 100, which is the best health you can imagine. Where would you put yourself on this scale, in terms of your own current health?

0 |-----| 50 |-----| 100
(Worst health) (Best health)

Participant's rating: _____

URINARY BOTHER

Overall, how big a problem/bother has your urinary function been for you during the last 4 weeks?
(e.g., difficulties starting or stopping the flow of urine, needing to urinate often, having a weak stream, leaking, wetting your pants)

- No problem.....1
 - Very small problem.....2
 - Small problem.....3
 - Moderate problem.....4
 - Big problem.....5
- (Circle one number)

PERCEIVED RISK

Compared to other men your **age**, what do you think your chances are of developing prostate cancer during your lifetime? Would you say you are...[READ LIST]

- ☐ at much less risk than others.....1
- ☐ at less risk than others.....2
- ☐ at the same risk as others.....3
- ☐ a higher risk than others.....4
- ☐ at much higher risk than others...5

CANCER WORRY

Overall, how worried are you about whether you will be diagnosed with prostate cancer?

- ☐ not at all worried
- ☐ a little worried
- ☐ somewhat worried
- ☐ extremely worried

GENERAL HEALTH BEHAVIORS

In addition to learning about the choices you are making about prostate cancer screening, we are also interested in other choices you have made related to your health. I will now ask you some questions about your health behaviors.

1. Have you ever been screened for **colorectal cancer**? ☐ yes ☐ no

If yes, what was the method used?

☐ FOBT ☐ flexible sigmoidoscopy ☐ colonoscopy ☐ barium enema
(fecal occult blood test)

Do you know the approximate date of your most recent test for colon cancer? ____/____/____

2. How would you describe your **cigarette** smoking habits?

[1]
Never smoked

[2]
Used to smoke

[3]
Now smoke → b. how many
cigarettes a day do you
smoke? _____ cigarettes per day

3. How many drinks of the following **alcoholic beverages** do you have during a typical week (including weekends)? (answer each line)

- a. _____ bottles or cans of beer
- b. _____ glasses of wine or wine coolers
- c. _____ mixed drinks or shots of liquor

4. How many times per week do you **exercise** for 20 minutes or more (for example, take a brisk walk)?

_____ times per week

GENERAL NUMERACY SCALE

I am going to switch gears for a minute. The next three questions are numerical items and not everyone answers them correctly. However, we ask them because we are interested in the best ways to communicate medical and numerical information to people.

1. Which of the following numbers represents the biggest risk of getting a disease?

☐ 1 in 100 ☐ 1 in 1,000 ☐ 1 in 10

2. Which of the following numbers represents the biggest risk of getting a disease?

☐ 1% ☐ 10% ☐ 5%

3. If the chance of getting a disease is 10%, how many people would be expected to get the disease:

- a. Out of 100? _____ [Answer: 10]
- b. Out of 1,000? _____ [Answer: 100]

DEMOGRAPHIC INFORMATION

I would like to ask you some questions about your background.

1. What is your date of birth? _____ month _____ day _____ year

2. What is your marital status? [DON'T READ LIST]

_____ never married _____ divorced
_____ married _____ widowed
_____ living in a marriage-like relationship _____ other: _____
_____ separated

3. Do you have a regular doctor? _____ yes _____ no

4. Do you have health insurance? _____ yes _____ no

IF YES: Is the insurance:

_____ Private (i.e., paid for by employer, family member's employer, or oneself;
e.g., commercial (bc/bs), HMO, Military/champus, PPO)
_____ Public (e.g., Medicaid, medicare)
_____ Combination of public and private (e.g., medicare plus 'gap' insurance that
was purchased)
_____ Other: _____

5. How many years of school have you completed? [DON'T READ LIST]

_____ 8th grade or less _____ some college
_____ some high school _____ college graduate
_____ high school graduate or GED _____ graduate work
_____ graduate degree

6. Are you currently employed? [DON'T READ LIST]

_____ Not employed _____ Retired _____ Full-time employed _____ Part-time employed

7. To what ethnic group do you belong? Hispanic or Latino _____ Not Hispanic or Latino _____

8. To which racial group do you belong? [Don't read list]

_____ white _____ Native American or Alaska Native
_____ black or African American _____ Native Hawaiian or Other Pacific Islander
_____ Caribbean or West Indian _____ Other: _____
_____ Asian

9. What is your total household income? [Don't read list]

_____ under \$25,000 _____ \$76,000-\$100,000 _____ Over \$150,000
_____ \$26,000-\$50,000 _____ \$101,000-\$150,000
_____ \$51,000-\$75,000

AT INTERVIEW CLOSE: [RANDOMIZATION OCCURS HERE.]

UC participants will not receive an intervention. Following enrollment and the T0 interview, UC participants will be called to complete the T1 and T2 follow-up interviews.

Print participants will receive the booklet within in several days of completing the T0 interview. The importance of reading it shortly after receiving it will be stressed.

Web participants will be given the website address, a secure password, and instructions for using the website. In addition, we will mail this same information as a reminder. For men without easy computer access, we will supply addresses of convenient libraries with free Internet access.

Thank you very much for your time today. Do you have any questions about the project at this point?